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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,775	01/07/2002	John A. Gelardi	PRG 01-3	4137

7590

01/07/2004

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EXAMINER
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FIDEI, DAVID

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 01/07/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/040,775

Applicant(s)

GELARDI ET AL. *ch*

Examiner

David T. Fidei

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 10-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,8 and 9 is/are rejected.
- 7) ☒ Claim(s) 3-7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Election/Restrictions***

1. Claims 10-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 12.

2. Applicant's election with traverse of claims 1-9 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the basis for the requirement has been obviated by applicant's amendment of the claim. This is not found persuasive because it is not seen how the amendment obviates the previous requirement. A package is recited in claim 1 that does not include the features, or steps recited in the method claim 10. Also the subcombination claim 17 includes features of the molded locking element not required in package claim 1.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1, 2 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The package interior of claim 2 has no antecedent basis.

As to claim 9, the paperboard portion is defined as laminated with a polymeric material. Since a polymeric material is always a plastic, it is unclear if the paperboard portion is a flexible paperboard or a plastic as recited in claim 1. Claim 1 seeming to imply the material is one or the other, i.e., a paperboard or plastic portion, but not both. Hence, claim 9 casts confusion on the scope of claim 1.

***Claim Construction***

5. In analyzing applicant's invention as set out in the pending claims, the examiner sets forth the following to aid in understanding the application of the prior art herein. Claims are to be given their broadest reasonable during prosecution, see *In re Priest*, 582 F.2d 33, 37 USPQ

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11, 15 (CCPA 1978), and limitations from the specification will not be read into the claims, see, e.g. In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), see MPEP 2106.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

7. Claims 1, 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolfe (Patent no. 6,021,901). A unit dose package is disclosed comprising a plastic portion (column 3, line 48) formed as a series of contiguous panels 14, 12 having attached thereto a locking element 32, 34 (Column 4 line 12) and the lock element includes a release element defined by members 36, 38, see column 4, lines 50-55.

As to claim 2, structures 70, 72, 74 and 76 are disclosed for containing unit doses within the interior of the package.

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8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Allison (Patent no. 4,890,742). A unit dose package comprising a plastic portion formed as a series of contiguous panels 4 and 5. A locking element is defined by members 26 and a release element by button 22.

As to claim 2, upwardly extending wall means defines an interior chamber for receiving pills, see column 1, lines 46-48, equivalent to the structure for containing unit doses in as much as is recited in the claim.

9. Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al (Patent no. 6,491,211). A unit dose package is disclosed in figure 3 comprising a flexible or plastic portion 101A formed as a series of contiguous panels having attached thereto a locking element 178 (see column 5, line 12) and a release element 160 (column 5, line 2).

As to claim 2, the side walls, top and bottom walls of package 100 defines a structure for containing unit doses within the package interior.

As to claims 8 and 9, column 3, lines 10-20 contemplates bleached or unbleached paperboard. The recitation drawn to the manner in which the paper is formed, i.e., from C1S or C2S, is of no patentable moment.

A "product by process" claim is directed to the product per se, no matter how actually made, *In re Hirao*, 190 USPQ 15 at 17 (footnote 3). See also *In re Brown*, 173 USPQ 685; *In re Luck*, 177 USPQ 523; *In re Fessmann*, 180 USPQ 324; *In re Avery*, 186 USPQ 161; *In re Wertheim*, 191 USPQ 90; and *In re Marosi et al*, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by process" claim, and that an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it which is recited in the claim. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

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As to claim 9, Evans et al contemplates a polymeric film, in col. 3, line 14.

10. Claims 1 and 2 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The Publication to Gelardi (Pub no. US 2003/0015438), as sole inventor, discloses a single unit dose package having a paperboard portion formed as cover 11 with a series of panels including a blister 35. Attached thereto is a locking element including a lock element and a release element,.

As to claim 2 structure 9 is for containing unit doses within the package

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(g) as being anticipated by Gelardi (Pub no. US 2003/0015438).

Present claims 1 and 2 recite nothing that distinguishes over the Publication to Gelardi (Pub no. US 2003/0015438).

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Gelardi (Pub no. US 2003/0015438).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

***Allowable Subject Matter***

13. Claims 3-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**REPLY BY APPLICANT OR PATENT OWNER TO THIS OFFICE ACTION**

14. “In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to every ground of objection and rejection in this Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. The applicant’s or patent owner’s reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section. The reply must be reduced to writing (emphasis added)”, see 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

Pointing out specific distinctions means clearly indicating in the written response what features/elements or distinctions have been added to the claim/claims, where support is found in the specification for such recitations and how these features are not shown, taught, obvious or inherent in the prior art.

If no amendments are made to claims as applicant or patent owner believes the claims are patentable without further modification, the reply must distinctly and specifically point out the supposed errors in the examiner’s action and must respond to every ground of objection and rejection in the prior Office Action in the same vain as given above, 37 CFR 1.111 (b) & (c), M.P.E.P. 714.02.

The examiner also points out, due to the change in practice as affecting final rejections, older decisions on questions of prematurity of final rejection or admission of subsequent amendments do not necessarily reflect present practice. “Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based

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on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)” (emphasis mine), see MPEP 706.07(a).

**Conclusion**

15. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, “should be directed to the group clerical personnel and not to the examiners. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information without contacting the examiners”, M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, email [CustomerService3700@uspto.gov](mailto:CustomerService3700@uspto.gov) .

Any inquiry concerning the MERITS of this examination from the examiner should be directed to David T. Fidei whose telephone number is (703) 308-1220. The examiner can normally be reached on Monday - Friday 6:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mickey Yu can be reached at (703) 308-2672.

Effective Monday morning, August 4, 2003, all official faxes for the TCs will be received in one central location in the Office. In cooperation with the Customer Service Goal Team, a new central official fax number (703-872-9306) has been established for use by the TCs. An OG notice will be issued and the Website updated to alert PTO customers of the new fax number. Official standalone (non-RightFax) fax machines will be removed from the TC fax centers, their phone numbers auto-forwarded to a single RightFax account, and faxes printed in the centralized fax center.



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Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 305-8497
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Fee Increase Questions	(703) 305-5125
Intellectual Property Questions	(703) 305-8217
Petitions/Special Programs	(703) 305-9282
Terminal Disclaimers	(703) 305-8408

If the information desired is not provided above, or has been changed, please do not call the examiner (this is the latest information provided to him) but the general information help line below.

Information Help line	1-800-786-9199
Internet PTO-Home Page	<a href="http://www.uspto.gov/">http://www.uspto.gov/</a>



David T. Fidei  
Primary Examiner  
Art Unit 3728

dtf

December 29, 2003